

Applicant or Patentee: Katherine High *et al.*  
Application or Patent No.: Not Yet Assigned  
Filed or Issued: June 8, 2000  
For: **METHODS FOR PREVENTING FORMATION OF  
INHIBITORY ANTIBODIES IN THE SETTING OF GENE  
THERAPY**

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) and 1.27(d)) - NONPROFIT ORGANIZATION**

NAME OF ORGANIZATION: The Children's Hospital of Philadelphia  
ADDRESS OF ORGANIZATION: 34th & Civic Center Boulevard  
Philadelphia, Pennsylvania 19104-4318

TYPE OF ORGANIZATION:

- ☐ University or other institution of higher education.  
☒ Tax exempt under Internal Revenue Service Code (26 USC 501(a) and 501(c)(3)).  
☐ Nonprofit scientific or educational under statute of state of the United States of America.  
Name of State \_\_\_\_\_  
Citation of Statute \_\_\_\_\_  
☐ Would qualify as tax exempt under Internal Revenue Code (26 USC 501(a) and 501(c)(3) if located in the United States of America.  
☐ Would qualify as nonprofit scientific or educational under statute of state of United States of America if located in the United States of America.  
Name of State \_\_\_\_\_  
Citation of Statute \_\_\_\_\_

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees under Sections 41(a) and (b) of Title 35, United States Code, with regard to the invention of the above-identified patent or patent application.

I hereby declare that U.S. rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above-identified invention.

If the rights held by the nonprofit organization are not exclusive, each individual concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

\*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 CFR 1.27).

FULL NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in the status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING  
TITLE IN ORGANIZATION  
ADDRESS OF PERSON SIGNING

David E. Pleasure, M.D.  
Director, Joseph Stokes, Jr., Research Institute  
Abramson Pediatric Research Center  
The Children's Hospital of Philadelphia  
34th Street and Civic Center Blvd.  
Philadelphia, PA 19104-3147

SIGNATURE \_\_\_\_\_

DATE: \_\_\_\_\_

6/7/00

**DECLARATION AND POWER OF ATTORNEY**  
(Related Application)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

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THE SETTING OF GENE THERAPY**

the specification of which is attached hereto and/or was filed on June 8, 2000 as Application No.: \_\_\_\_\_.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to herein.

I acknowledge the duty to disclose information which is material to patentability in accordance with Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d), of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

**FOREIGN PRIORITY APPLICATION(S)**

\_\_\_\_\_  
(Number) (Country) (Day/month/year filed)

**Priority Claimed**  
☐ Yes ☐ No

\_\_\_\_\_  
(Number) (Country) (Day/month/year field)

**Priority Claimed**  
☐ Yes ☐ No

$$\begin{aligned} & \left\{ \begin{array}{l} \mathbb{R}^{(m)} \\ \mathbb{R}^{(m)} \\ \vdots \\ \mathbb{R}^{(m)} \end{array} \right\} \left\{ \begin{array}{l} \mathbb{R}^{(m)} \\ \mathbb{R}^{(m)} \\ \vdots \\ \mathbb{R}^{(m)} \end{array} \right\} \left\{ \begin{array}{l} \mathbb{R}^{(m)} \\ \mathbb{R}^{(m)} \\ \vdots \\ \mathbb{R}^{(m)} \end{array} \right\} \left\{ \begin{array}{l} \mathbb{R}^{(m)} \\ \mathbb{R}^{(m)} \\ \vdots \\ \mathbb{R}^{(m)} \end{array} \right\} \\ & \left\{ \begin{array}{l} \mathbb{R}^{(m)} \\ \mathbb{R}^{(m)} \\ \vdots \\ \mathbb{R}^{(m)} \end{array} \right\} \left\{ \begin{array}{l} \mathbb{R}^{(m)} \\ \mathbb{R}^{(m)} \\ \vdots \\ \mathbb{R}^{(m)} \end{array} \right\} \left\{ \begin{array}{l} \mathbb{R}^{(m)} \\ \mathbb{R}^{(m)} \\ \vdots \\ \mathbb{R}^{(m)} \end{array} \right\} \left\{ \begin{array}{l} \mathbb{R}^{(m)} \\ \mathbb{R}^{(m)} \\ \vdots \\ \mathbb{R}^{(m)} \end{array} \right\} \end{aligned}$$

Philadelphia, Pennsylvania 19103. Please direct all communications and telephone calls to **Kathryn Doyle, Ph.D., J.D.** at (215) 965-1284.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full name of sole  
or first inventor **Katherine A. High**

Inventor's Signature \_\_\_\_\_

Date \_\_\_\_\_

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Full name of  
second inventor **Paul A. Fields**

Inventor's Signature \_\_\_\_\_

Date \_\_\_\_\_

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Full name of  
third inventor Valder R. Arruda

Inventor's Signature \_\_\_\_\_

Date \_\_\_\_\_

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Full name of  
fourth inventor Roland W. Herzog

Inventor's Signature \_\_\_\_\_

Date \_\_\_\_\_

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Citizenship Germany

Post Office Address 100 East Glenolden Avenue, No. L2

Glenolden, PA 19036

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